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PATENT

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re Application of:  
Lei Yu

Serial No.: 09/626,616

Filed: July 27, 2000

For: POLYNUCLEOTIDE ENCODING MU  
OPIOID RECEPTOR

Group Art Unit: 1647

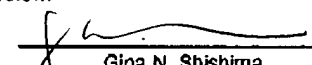
Examiner: R. Landsman

Attorney Docket. No.: INDA:005USD1/GNS

#10  
A.G.-J  
3/11/02

CERTIFICATE OF MAILING  
37 C.F.R. 1.8

I hereby certify that this correspondence is being deposited with the U.S. Postal Service as First Class Mail in an envelope addressed to: Assistant Commissioner for Patents, Washington, D.C. 20231, on the date below:

10/19/01 Date  Gina N. Shishima

DECLARATION OF LEI YU, PH.D.

UNDER 37 C.F.R. § 1.131, REGARDING CHEN AND FUKUDA 1993 REFERENCE

I, Lei Yu, hereby declare as follows:

1. I am the sole inventor of the subject matter of all claims currently pending in the referenced patent application.
2. I understand that the United States Patent and Trademark Office Examiner has found the claimed subject matter of the referenced application to be anticipated by the publications of Chen *et al.* Mol. Pharmacol. 44:8-12, 1993 ("Chen reference") and Fukuda *et al.*, FEBS Letters 327:311-314, 1993 ("the Fukuda 1993 reference"). Claims 44-47 have been rejected over these references.

3. I am submitting this declaration to set forth evidence that I invented the subject matter of the claimed invention prior to the publication dates of the Chen reference and the Fukuda 1993 reference.

4. Submitted as Exhibit 1 to this declaration is the Chen reference, which reports my inventive work concerning a rat  $\mu$ -opioid receptor, including its characterization by nucleic acid and amino acid sequences and its binding activity. (Exhibit 1, pages 8-11).

5. I am the only inventor co-author of the Chen reference. The other named co-authors of the article—Yan Chen, Anton Mestek, Jian Liu, and Joyce Hurley—did not take part in the conception of any of the subject matter disclosed and claimed in the referenced patent application, and are accordingly not co-inventors of the patent application.

6. In conjunction with the studies reported in the Chen reference, Yan Chen was a graduate student in my laboratory at Indiana University School of Medicine in Indianapolis, Indiana. Mr. Chen is named as an author on this paper because he performed the library screening, DNA sequencing, and some of the assays including binding studies with respect to a rat  $\mu$  opioid receptor. However, he did this under my direction and did not take part in the conception of any of the subject matter disclosed and claimed in the referenced patent application.

7. Anton Mestek was a postdoctoral fellow in my laboratory. He contributed technical assistance related to DNA sequencing and the functional assays involving the rat  $\mu$  opioid receptor. However, Dr. Mestek did not participate in the conception of any of the subject matter disclosed and claimed in the referenced patent application.

8. In regard to the Chen reference, Jian Liu was a research fellow in my laboratory who also helped in performing the DNA sequencing of the rat  $\mu$  opioid receptor clone and functional assays

involving the clone. However, Ms. Liu did not participate in the conception of any of the subject matter disclosed and claimed in the referenced patent application.

9. Joyce Hurley was a graduate student in my laboratory. She assisted with doing the functional assays with the rat  $\mu$  opioid receptor. However, Ms. Hurley did not participate in the conception of any of the subject matter disclosed and claimed in the referenced patent application.



10. All of the work described in the Chen reference was conducted in the United States.

11. The concept of isolating, sequencing, characterizing rat and human  $\mu$  opioid receptors, and using such receptors in screening assays, which forms the basis for the claims and material of the present application, was derived solely and independently by myself. The other co-authors of the Chen reference did not participate in the conception of the subject matter claimed in the present patent application.

12. In view of the above, the Chen reference is evidence that I, as sole inventor co-author of the paper, invented the portions of the Chen reference that relate to the isolation and sequencing of the rat  $\mu$  opioid receptor. Thus, the Chen reference should not be prior art against the above-referenced patent application.

13. Submitted as Exhibit 2 to this declaration is the 1993 Fukuda reference with the cover page of the journal showing it was published in the 2 August 1993 volume of FEBS Letters.

14. Further, the Chen reference is evidence that I must have invented this aspect of the claimed invention and properly tested it at least as early as the date of its submission, May 4, 1993. The Chen reference is evidence of invention of the claimed invention prior to the Fukuda 1993 reference. Therefore, the Fukuda 1993 reference should not be prior art against the above-referenced patent application.



15. I hereby declare that all statements made of my own knowledge are true and all statements made on information are believed to be true and further that the statements were made with the knowledge that willful false statements and the like so made are punishable by fine or

imprisonment or both under § 1001 of Title 18 of the United States Code, and that such willful false statements may jeopardize the validity of this application or any patent issued thereon.

Date: Oct. 17, 2001

Lei Yu  
Lei Yu, Ph.D.